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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,900	06/26/2001	Kenneth W. Rake	IFLOW.2CP2F3C1	2814
20995	11/15/2006			
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER REICHLE, KARIN M	
			ART UNIT 3761	PAPER NUMBER

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,900

Applicant(s)

RAKE ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 19, 23, 24, 30, 33 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19, 23, 24, 30, 33 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-30-06 has been entered.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

3. The drawings are objected to because the label of the x-axis in Figure 58 filed 8-1-03 is incorrect. Also, Figures 56-59 described as plots of the data of Tables 1 and 2 do not appear to be accurate plots of the data of Tables 1 and 2. See, for example, Table 2, an output pressure of 3.6 psi at 90 cc appears to be incorrectly plotted. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure

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or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. Claims 14-17, 19, 23-24, 30, 33, and 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 14, 19 and 23 now require a spring rate and working length of the spring(s), the platen and the interior surface be configured to compress the bag to expel fluid therefrom when the platen is moving in said first direction such that an outlet pressure of the fluid is substantially constant over substantially the entire dispensation cycle of the pump. New claims 37-39 defined such outlet pressure of the fluid which is substantially constant over substantially the entire dispensation cycle of the pump further as not fluctuating more than 10% during the first 90% of the dispensation cycle. Applicants rely on Tables 1 and 2

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on pages 53-54 and the Figures 57-60, of which Figures 56-59 are described as graphical representations of the data of such Tables, see, however, the discussion in paragraph 3 supra.

First it is noted that the species elected in this application was that of Figures 52-55 and Figure 60 is directed to the other species, see, e.g., page 38, line 28-page 39, line 34 of the instant application. Second, the data of such Tables is described as **the output fluid pressure from the bag as measured as the volume in the bag is decreased over the dispensation cycle.**

Compare to the claim language, i.e. an **outlet pressure of the fluid** is substantially constant over substantially the entire **dispensation cycle of the pump**. Furthermore, Table 1 in which a 50 cc bag was used shows such output pressure being 5.0 psi at the beginning of such cycle, i.e. 0 cc volume expelled, and 4.45 psi after the first 90% of the cycle which amounts to more than a 10%, i.e. more than 0.5 psi, fluctuation during the first 90% of such cycle, i.e. 45 cc volume expelled, and Table 2 in which a 100 cc bag was used shows such output pressure being 5.1 psi at the beginning of such cycle, i.e. 0 cc volume expelled, and 3.6 psi after the first 90% of such cycle which amounts to more than a 10%, i.e. more than 0.51 psi, fluctuation during the first 90% of the cycle, i.e. 90 cc volume expelled (It is again noted that the Figures do not appear to reflect the data/fluctuations set forth in the Tables, see paragraph 3, supra). However this does not appear to be what is claimed in the amended and new claims, as best understood, see also paragraph 5 infra. While the application, as originally filed, also sets forth, e.g., in the sentence bridging pages 51-52, “a..substantially constant **medication output pressure until the bag is substantially collapsed**”, e.g., at page 53, lines 35-37, “Figure 57 illustrates the remarkably **steady output pressure of the medication contained in the medication bag** 406 during the **dispensation cycle by the platen pump** 400”, and, e.g., a 11% fluctuation of the output fluid

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pressure of the medication bag after the first 45 cc is expelled, i.e. first 90% of the dispensation cycle of the bag, in Table 1 and a 29% fluctuation of the output fluid pressure of the medication bag after the first 90 cc is expelled, i.e. first 90% of the dispensation cycle of the bag, in Table 2, this also does not appear to be what is claimed in the amended and new claims as best understood. If Applicants maintain such language, the portion of the original specification relied upon for the full scope of the combination claimed in each claim in a single embodiment should be set forth. See Claim Language Interpretation section *infra*.

5. Claims 14-17, 19, 23-24, 30, 33, and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 19 and 23 “an outlet pressure of the fluid”. However it is not clear what structure of the invention includes such “outlet”. The outlet of the pump? The outlet of the bag? The outlet of the outlet tube (claim 24)? Claims 14, 19 and 23 also claim such pressure “is substantially constant over substantially the entire dispensation cycle of the pump”. Such claim language has not been specifically defined. Note the discussion in paragraph 4 *supra*. Therefore the terms of the claim will be given their common, i.e. dictionary, definition as is consistent with the specification. “Constant” as defined by the dictionary is “unchanging in nature, value, extent; invariable”, and “entire” means “whole”. In other words the independent claims require such pressure be substantially unchanging over substantially the whole cycle. Yet claims 37-39 which depend from these claims, i.e. further define/narrow the invention of such claims, define such pressure as being no more than 10% fluctuation over the first 90% of the cycle thereby inferring the % pressure fluctuation and/or cycle % of claims 14, 19 and 23 is more, e.g. more than 10%

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fluctuation and/or over a shorter % of the cycle, and thereby, the pressure substantially changing over substantially the whole cycle. Therefore, the outlet pressure as set forth in the claims is inconsistent/unclear. A clear, consistent description of such pressure should be set forth. See Claim Language Interpretation section supra.

Claim Language Interpretation

6. It is noted that none of the claim language has been specifically defined. Therefore the terms of the claim will be given their common, i.e. dictionary, definition as is consistent with the specification. "Platen" as defined by the dictionary is "One of the two flat members of the printing press that serves to position the paper and hold it against the inked type". Since this is not consistent with the specification, "platen" will be interpreted as a member which is capable of exerting pressure. See also discussion infra. Due to the lack of clarity discussed in paragraph 5 infra, the "outlet" and thereby, "an outlet pressure of said fluid", will be interpreted to read on the outlet of any structure of the invention, e.g. the pump or the bag or the outlet tube. Since "an outlet pressure of the fluid which is substantially constant over substantially the entire dispensation cycle of the pump" has not been defined by the original specification, i.e. lack of the specific terminology "an outlet pressure of the fluid which is substantially constant over substantially the entire dispensation cycle of the pump" in the originally filed specification, and specifics, e.g. numerical ranges, which constitute "an outlet pressure of the fluid which is substantially constant" and "substantially the entire dispensation cycle of the pump", note paragraph 4 supra, as well as the inconsistency/lack of clarity of such terminology discussed in paragraph 5 infra, such terminology of claims 14, 19 and 23 will be interpreted to include

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fluctuations of more than 10% but no more than about 29% and/or during portions of the cycle less than first 90% but no less than 1% of the dispensation cycle in light of claims 37-39 and the data of Tables 1 and 2 as originally filed. With regard to such claim language of claims 14, 19 and 23 and claims 37-39 and the discussion in paragraph 4 *supra*, see also MPEP 2163.06, I. Therefore, the filing date accorded the claims would be considered to be 6-26-06. However, it is noted that even if the claimed subject matter were not considered new matter, the earliest filed application from which priority is claimed, i.e. 07/824,855, still does not disclose the subject matter relied upon for support of the amended and new claims, e.g. the earliest possible filing date would be 6-15-92.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 14-17, 19, 23-24, 30, 33, and 36-39 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Elson '476.

Claims 14-17, 19, 23, 30, 33 and 36: See the Claim Language Interpretation section *supra*, and, e.g., the Figures, especially Figure 11, and col. 1, lines 5-9, col. 2, lines 30-31 and col. 2, lines 34-60, col. 3, lines 1-6, lines 23-34 and 51-65, col. 4, lines 21-24 and 38-50 and col. 4, line 56-col. 5, line 11 of '476: 12 and 16 are threadably engaged shells of generally circular outer shape, the "platen", see Claim Interpretation section *supra*, is 18 with nonplanar surface, the exterior of 62, 64, which is "complementary", i.e. defined as "forming or serving as a complement, completing", to the inner surface, i.e. the inner surface of 22, 24, of shell 12, i.e.

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which shell and platen surfaces have a substantially planar central portion, e.g. 24 and 62, respectively, and a nonplanar annular portion, e.g. 22 and 64, respectively, and 38 is a spring fastened to shell 16. The space defined between the platen and the shell holds a fluid bag 28 therein. Claims 14, 19 and 23 now require the spring rate and working length of the at least one spring, the platen and the interior surface are configured to compress the bag to expel fluid therefrom when the platen is moving in said first direction such that “an outlet pressure of the fluid” is substantially constant over substantially the entire dispensation cycle of the pump, i.e. function, properties or capabilities of the claimed structure. It is the Examiner’s first position that the ‘476 reference at the cited portions, especially Figure 14, teaches such function, properties or capabilities because Figure 14 shows that the delivery pressure, i.e. the outlet pressure of the device, does not vary more than about 5% over 100% of the cycle. In any case, i.e. the Examiner’s second position, since ‘476 teaches the claimed structure and such delivery pressure fluctuation over 100% of the cycle, that as best understood, there is sufficient factual evidence for one to conclude that the same structure of ‘476 also inherently includes the function, properties and capabilities as claimed in claims 14, 19 and 23.

Claim 24: See col. 4, lines 38-51 and Figures.

Claims 37-39: See the discussion of claims 14, 19 and 23 supra, Figure 14 and Claim Language Interpretation section supra, i.e. as best understood, ‘476 teaches an outlet pressure which does not fluctuate more than 10% during the first 90% of the cycle in Figure 14.

Response to Arguments

9. Applicant's remarks have been considered but are either deemed moot in that the issue discussed has not been repeated or deemed not persuasive in light of the discussion *supra*.

Conclusion

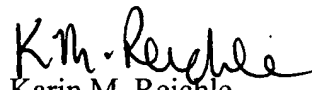
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art shows an infusion device with scissors mechanism.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
November 7, 2006